

10/088405

JC10 Rec'd PCT/PTO 18 MAR 2002
Sheet 1 of 2

Express Mail No. EV077493871US

Form PTO-1449 (Rev. 2-88)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 410718.90395	SERIAL NO. UNASSIGNED
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT CHANDRASEKAR, Baskaran et al.			
		FILING DATE 18 March 2002	GROUP		

U.S. PATENT DOCUMENTS

EXAMINER'S INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AMC	1	5,376,652	12/27/94	Norman	514	177	
AMC	2	5,866,561	2/2/99	Ungs	514	182	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
AMC	3	98/56312	12/17/98	WO				
AMC	4	00/12147	3/9/00	WO				
AMC	5	00/10552	3/2/00	WO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AMC	6	YOON YOUNG-SUP ET AL: "Local intraluminal infusion of oestradiol containing liposome in rat carotid balloon injury model." EUROPEAN HEART JOURNAL, vol. 19, no. ABST. SUPPL., August 1998 (1998-08), page 616; XP001014473; XXth Congress of the European Society of Cardiology; Vienna, Austria; August 22-26, 1998; ISSN: 0195-668X
AMC	7	ZHANG Y-Q ET AL: "EFFECTS OF GENDER AND ESTRADIOL TREATMENT ON FOCAL BRAIN ISCHEMIA", BRAIN RESEARCH, AMSTERDAM, NL, vol. 784, no. 1/2, 16 Feb 1998 (1998-02-16), pages 321-324, XP000884355; ISSN: 0006-8993
AMC	8	KAUFFMAN RAYMOND F ET AL: "Comparative effects of local vs. systemic administration of estrogen upon vascular responses to balloon injury." CIRCULATION, vol. 92, no. 8 SUPPL., 1995, page 1628; XP001014766; 68 th Scientific Session of the American Heart Association; Anaheim, CA; USA; November 13-16, 1995; ISSN: 0009-7322

EXAMINER <i>Alayn Lata</i>	DATE CONSIDERED <i>8/22/2005</i>
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Sheet 2 of 2

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
AML	✓	9	DATABASE BIOSIS Onlinel BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; May 1999 (199-05); PERROT-APPLANAT M: "Oestradiol and proliferation of vascular cells." Database accession no. PREV200000507148; XP002177140; abstract & THERAPIE (LONDON), vol. 54, no. 3, May 1999 (1999-05), pages 333-337, ISSN: 0040-5957				
AML	✓	10	DATABASE BIOSIS Onlinel BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1995 MIKKOLA TOMI ET AL: "17-beta-estradiol stimulates prostacyclin, but not endothelin-1, production in human vascular endothelial cells." Database accession no. PREV199598355998; XP002177141; abstract & JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM, vol. 80, no. 6, 1995, pages 1832-1836; ISSN: 0021-972X				
AML	✓	11	DATABASE BIOSIS Onlinel BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996 MIKKOLA TOMI ET AL: "Effect of physiological concentrations of estradiol on PGI-2 and NO in endothelial cells." Database accession no. PREV199799286811; XP002177142; abstract & MATURITAS, vol. 25, no. 2, 1996, pages 141-147; ISSN: 0378-5122				
AML	✓	12	CHANDRASEKAR, BASKARAN, (1) ET AL: "Coronary artery endothelial protection following local delivery of 17-beta estradiol during balloon angioplasty: A potential new pharmacological approach to improve long-term outcome of angioplasty." JOURNAL OF AMERICAN COLLEGE OF CARDIOLOGY, (FEB., 2000) VOL. 35, NO. 2, SUPPL. A, PP. 58A, MEETING INFO.: 29 TH ANNUAL SCIENTIFIC SESSION OF THE AMERICAN COLLEGE OF CARDIOLOGY, ANAHEIM, CA, USA. MARCH 12-15, 2000; XP001015229				
AML	✓	13	SELZMAN, CRAIG H. ET AL: "Estrogen replacement inhibits intimal hyperplasia and the accumulation and effects of transforming growth factor .beta.1." J. SURG. RES. (1998), 80(2), 380-385; XP001014759				
AML	✓	14	KEANY J. F. ET AL: "17BETA-ESTRADIOL PRESERVES ENDOTHELIAL VASODILATOR FUNCTION AND LIMITS LOW-DENSITY LIPOPROTEIN OXIDATION IN HYPERCHOLESTEROLEMIC SWINE" CIRCULATION, AMERICAN HEART ASSOCIATE, DALLAS, TX, US., vol 89, no. 5, May 1994 (1994-05), pages 2251-2259; XP001014735; ISSN: 0009-7322				
AML	✓	15	DATABASE BIOSIS Onlinel BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996; KUBLIK HEIKE ET AL: "Nasal absorption of 17-beta-estradiol from different cyclodextrin inclusion formulations in sheep." Database accession no. PREV199799383935; XP002177143; abstract & EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, vol. 42, no. 6, 1996, pages 320-324; ISSN: 0939-6411				
EXAMINER <i>Olegard Et al</i>				DATE CONSIDERED <i>8/22/2005</i>			
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Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/088,405
		Filing Date	March 11, 2002
		First Named Inventor	Baskaran Chadrasekar
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	201267.90011
Sheet	1	of	8

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature	Alyse Cotton	Date Considered	8/15/2015
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

8

Complete If Known

Application Number	10/088,405
Filing Date	March 11, 2002
First Named Inventor	Baskaran Chadrasekar
Group Art Unit	
Examiner Name	
Attorney Docket Number	201267.90011

O I P E

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PATENT & TRADEMARK OFFICE

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
AMC		Akishita, M., et al., "Estrogen Inhibits Cuff-induced Intima Thickening of Rat Femoral Artery: Effects on Migration and Proliferation of Vascular Smooth Muscle Cells," <i>Atherosclerosis</i> 130:1-10, 1997.	
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AMC		Asahara, T., et al., "Local Delivery of Vascular Endothelial Growth Factor Accelerates Reendothelialization and Attenuates Intima Hyperplasia in Balloon-injured Rat Carotid Artery," <i>Circulation</i> 91(11):2793-2801, 1995.	
AMC		Bauriedel, G., et al., "Migratory Activity of Human Smooth Muscle Cells Cultivated from Coronary and Peripheral Primary and Restenotic Lesions Removed by Percutaneous Atherectomy," <i>Circulation</i> 85(2):554-564, 1992.	
AMC		Bonan, R., et al., "Coronary Restenosis: Evaluation of a Restenosis Injury Index in a Swine Model," <i>Am. Heart J.</i> 126(6):1334-1340, 1993.	
AMC		Brewster, M.E., et al., "Use of 2-hydroxypropyl-betacyclodextrin as a Solubilizing and Stabilizing Excipient for Protein Drugs," <i>Pharm. Res.</i> 8(6):792-795, 1991.	
AMC		Chandrasekar, B. and Tanquay, J.F., "Local Delivery of 17-beta Estradiol Decreases Neointima Hyperplasia Following Coronary Angioplasty in Porcine Model," (submitted for publication).	
AMC		Chen, S.J., et al., "Estrogen Reduces Myointimal Proliferation after Balloon Injury of Rat Carotid Artery," <i>Circulation</i> 93(3):577-584, 1996.	
AMC		Chesebro, J.H., et al., "Restenosis after Arterial Angioplasty: A Hemorrhologic Response to Injury," <i>Am. J. Cardiol.</i> 60:10B-16B, 1987.	
AMC		Clowes, A.W., et al., "Kinetics of Cellular Proliferation after Arterial Injury: Smooth Muscle Cell Growth in the Absence of Endothelium," <i>Lab. Invest.</i> 49(3):327-333, 1983.	
AMC		Collins, P., et al., "Hemoglobin Inhibits Endothelium-dependent Relaxation to Acetylcholine in Human Coronary Arteries In Vivo," <i>Circulation</i> 87(1):80-85, 1993.	

Examiner Signature

Aliza Hutton

Date Considered

8/22/2002

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Application Number	10/088,405
Filing Date	March 11, 2002
First Named Inventor	Baskaran Chadrasekar
Group Art Unit	
Examiner Name	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 8 Attorney Docket Number 201267.90011

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
AMC	✓	Cooke, J.P. and Tsao, P.S., "Cytoprotective Effects of Nitric Oxide," Circulation 88(5):2451-2454, 1993.	
AMC	✓	Cornwell, T.L., et al., "Inhibition of Smooth Muscle Cell Growth by Nitric Oxide and Activation of cAMP-dependent Protein Kinase by cGMP," Am. J. Physiol. 267:C1405-C1413, 1994.	
AMC	✓	Currier, J.W. and Faxon, D.P., "Restenosis after Percutaneous Transluminal Coronary Angioplasty: Have We Been Aiming at the Wrong Target?", J. Am. Coll. Cardiol. 25(2):516-520, 1995.	
AMC	✓	Dai-Do, D., et al., "17-Beta Estradiol Inhibits Proliferation and Migration of Human Vascular Smooth Muscle Cells: Similar Effects in Cells from Postmenopausal Females and in Males," Cardiovas. Res. 32:980-985, 1996.	
AMC	✓	Dangas, G., and Fuster, V., "Management of Restenosis after Coronary Intervention," Am. Heart J. 132(2):428-436, 1996.	
AMC	✓	Doenicke, A., et al., "A Comparison of Two Formulations for Etomidate, 2-hydroxypropyl-beta-cyclodextrin (HPCD) and Propylene Glycol," Anesth. Analg. 79:933-939, 1994.	
AMC	✓	Fischell, T.A., et al., "Coronary Artery Vasoconstriction Routinely occurs after Percutaneous Transluminal Coronary Angioplasty: A Quantitative Arteriographic Analysis," Circulation 78(6):1323-1334, 1988.	
AMC	✓	Foegh, M.L., et al., "Estradiol Inhibition of Arterial Neointima Hyperplasia after Balloon Injury," J. Vasc. Surg. 19(4):722-726, 1994.	
AMC	✓	Frijlink, H.W., et al., "The Pharmacokinetics of Beta-cyclodextrin and 2-hydroxypropyl-beta-cyclodextrin in the Rat," Pharm. Res. 7(12):1248-1252, 1990.	
AMC	✓	Furchtgott, R.F. and Zawadzki, J.V., "The Obligatory Role of Endothelial Cells in the Relaxation of Arterial Smooth Muscle by Acetylcholine," Nature 288:373-376, 1980.	
AMC	✓	Geary, R.L., et al., "Conjugated Equine Estrogens Inhibit Progression of Atherosclerosis but have no Effect on Intimal Hyperplasia or Arterial Remodeling Induced by Balloon Catheter Injury in Monkeys," J. Am. Coll. Cardiol. 31(5):1158-1164, 1998.	

Examiner Signature

Alicia L. Lotton

Date Considered

8/22/02

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Sheet 4 of 8

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Application Number	10/088,405
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First Named Inventor	Baskaran Chadrasekar
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AML	—	Gilligan, D.M., et al., "Effects of Physiological Levels of Estrogen on Coronary Vasomotor Function in Postmenopausal Women," Circulation 89(6):2545-2551, 1994.	—
AML	✓	Hayashi, Y., et al., "Functional and Anatomical Recovery of Endothelium after Denudation of Coronary Artery," Am. Physiol. Soc. H1081-H1090, 1988.	—
AML	—	Hayashi, T., et al., "Estrogen Increases Endothelial Nitric Oxide by a Receptor-mediated System," Biochem. Biophys. Res. Commun. 214(3):847-855, 1995.	—
AML	✓	Hishikawa, K., et al., "Up-regulation of Nitric Oxide Synthase by Estradiol in Human Aortic Endothelial Cells," FEBS Let. 360:291-293, 1995.	—
AML	—	Hoon, T.J., et al., "Bioequivalence of a 17-beta Estradiol Hydroxypropyl-beta-cyclodextrin Complex in Postmenopausal Women," J. Clin. Pharmacol. 33:1116-1121, 1993.	—
AML	—	Hyder, S.M., et al., "Uterine Expression of Vascular Endothelial Growth Factor is Increased by Estradiol and Tamoxifen," Cancer Res. 56(17):3954-3960, 1996.	—
AML	✓	Iafrati, M.D., et al., "Estrogen Inhibits the Vascular Injury Response in Estrogen Receptor alpha-deficient Mice," Nat. Med. 3(5):545-548, 1997.	—
AML	✓	Karas, R.H., et al., "Human Vascular Smooth Muscle Cells Contain Functional Estrogen Receptor," Circulation 89(5):1943-1950, 1994.	—
AML	—	Karas, S.P., et al., "Coronary Intimal Proliferation after Balloon Injury and Stenting in Swine: An Animal Model of Restenosis," J. Am. Coll. Cardiol. 20(2):467-474, 1992.	—
AML	✓	Kawano, H., et al., "Gender Differences in Improvement of Endothelium-dependent Vasodilation after Estrogen Supplementation," J. Am. Coll. Cardiol. 30(4):914-919, 1997.	—
AML	✓	Kim-Schulze, S., et al., "Expression of an Estrogen Receptor by Human Coronary Artery and Umbilical Vein Endothelial Cells," Circulation 94(6):1402-1407, 1996.	—

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Sheet 5 of 8

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Group Art Unit	
Examiner Name	
Attorney Docket Number	201267.90011

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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AMC		Kim-Schulze, S., et al., "Estrogen Stimulates Delayed Mitogen-Activated Protein Kinase Activity in Human Endothelial Cells via an Autocrine Loop that Involves Basic Fibroblast Growth Factor," Circulation 98:413-421, 1998.	
AMC		King, S.B. III, et al., "Endovascular beta-radiation to Reduce Restenosis after Coronary Balloon Angioplasty: Results of the Beta Energy Restenosis Trial (BERT)," Circulation 97:2025-2030, 1998.	
AMC		Kolodgie, F.D., et al., "Estradiol Attenuates Directed Migration of Vascular Smooth Muscle Cells In Vitro," Am. J. Pathol. 148(3):969-976, 1996.	
AMC		Kraskinski, K., et al., "Estradiol Accelerates Functional Endothelial Recovery after Arterial Injury," Circulation 95(7):1768-1772, 1997.	
AMC		Kristensson, J.K., et al., "Dexamethasone-cyclodextrin-polymer Co-complexes in Aqueous Eye Drops: Aqueous Humor Pharmacokinetics in Humans," Invest. Ophthalmol. Vis. Sci. 37(6):1199-1203, 1996.	
AMC		Kuiper, G.G.J.M., et al., "Cloning of a Novel Estrogen Receptor Expressed in Rat Prostate and Ovary," Proc. Natl. Acad. Sci. USA 93:5925-5930, 1996.	
AMC		Kullo, I.J., et al., "Enhanced Endothelium-dependent Relaxations after Gene Transfer of Recombinant Endothelial Nitric Oxide Synthase to Rabbit Carotid Arteries," Hypertension 30(3):314-320, 1997.	
AMC		Levine, R.L., et al., "Medroxyprogesterone Attenuates Estrogen-mediated Inhibition of Neointima Formation after Balloon Injury of the Rat Carotid Artery," Circulation 94(9):2221-2227, 1996.	
M		Lindner, V., et al., "Regrowth of Arterial Endothelium: Denudation with Minimal Trauma Leads to Complete Endothelial Cell Growth," Lab. Invest. 61(5):556-563, 1989.	
AMC		Lindner, V., et al., "Basic Fibroblast Growth Factor Stimulates Endothelial Regrowth and Proliferation in Denuded Arteries," J. Clin. Invest. 85:2004-2008, 1990.	
AMC		Lindner, et al., "Increased Expression of Estrogen Receptor- α mRNA in Male Blood Vessels after Vascular Injury," Cir. Res. 83:224-229, 1998.	

Examiner Signature

Alayna Cotten

Date Considered

8/12/02

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SHEET

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Group Art Unit	
Examiner Name	

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AMC	-	Losordo, D.W., et al., "Variable Expression of the Estrogen Receptor in Normal and Atherosclerotic Coronary Arteries of Premenopausal Women." Circulation 89(4):1501-1510, 1994.	
AMC	-	Ludmer, P.L., et al., "Paradoxical Vasoconstruction Induced by Acetylcholine in Atherosclerotic Coronary Arteries," N. Eng. J. Med. 315(17):1046-1051, 1986.	
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AMC	-	Malekianpour, M., et al., "Abnormal Coronary Vasomotion and Angina after Successful Coronary Angioplasty," Circulation 94(8):I-560, 1996 (Abstract).	
AMC	-	Mancini, G.B.J., et al., "Automated Quantitative Coronary Arteriography: Morphologic and Functional Validation In Vivo of a Rapid Digital Angiographic Method," Circulation 75(2):452-460, 1987.	
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Alayn Lott

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Application Number	10/088,405
Filing Date	March 11, 2002
First Named Inventor	Baskaran Chadrasekar
Group Art Unit	
Examiner Name	
Attorney Docket Number	201267.90011



OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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First Named Inventor	Baskaran Chadrasekar
Group Art Unit	
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
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		FILING DATE 07/24/2002	GROUP 3762

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Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date
<i>AM</i>	<i> </i>	5,180,368	01-29-93	<i> </i>	<i> </i>	<i> </i>	<i> </i>
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							Yes No
AM	—	WO00/01726	10-01-00	—	—	—	—
AM	—	WO00/55318	21-09-00	—	—	—	—

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